



Charter

Secretary's Advisory Committee on Xenotransplantation

Purpose

The Department of Health and Human Services (DHHS; also, Department) has a vital role in safeguarding public health while fostering the development of promising strategies to treat tissue destruction, organ failure and other public health needs. The Secretary's Advisory Committee on Xenotransplantation (Committee) considers the full range of complex scientific, medical, social, and ethical issues and the public health concerns raised by xenotransplantation, including ongoing and proposed protocols, and makes recommendations to the Secretary of Health and Human Services (Secretary) on policy and procedures. The recommendations of the Committee will facilitate DHHS efforts to develop an integrated approach to addressing emerging public health issues in xenotransplantation.

Authority

42 U.S.C. 217a; section 222 of the Public Health Service Act, as amended. The Committee is governed by the provisions of Public law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Function

The Secretary's Advisory Committee on Xenotransplantation shall advise the Secretary, through the Assistant Secretary for Health, on all aspects of the scientific development and clinical application of xenotransplantation. The Committee's charge includes the following activities:

- Advise the Department on the current state of knowledge regarding xenotransplantation.
- Be informed about current and proposed xenotransplantation clinical trials in order to identify and discuss the medical, scientific, ethical, legal, and/or socioeconomic issues raised by these clinical trials.
- Advise the Department on the potential for transmission of infectious diseases as a consequence of xenotransplantation.
- Advise the Department on policies relevant to xenotransplantation, including the need for changes to the *PHS Guideline on Infectious Disease Issues in Xenotransplantation*.
- Discuss additional scientific, medical, public health, ethical, legal, and socioeconomic issues, including international policies and developments, that are relevant to xenotransplantation.

Structure

The Committee shall consist of 18 voting members, including the Chair, appointed by the Secretary or designee. Members shall be selected from authorities knowledgeable in fields such as xenotransplantation, epidemiology, virology, microbiology, infectious diseases, molecular biology, veterinary medicine, immunology, transplantation surgery, public health, applicable law, bioethics, social sciences, psychology, patient advocacy, and animal welfare. Of the appointed members, at least one shall be a current member of the Food and Drug Administration (FDA) Biologic Response Modifiers Advisory Committee and at least one shall be a current member of the Centers for Disease Control and Prevention (CDC) Healthcare Infection Control Practices Advisory Committee.

In addition, the Committee shall include nonvoting ex officio members from relevant DHHS components, including the Office of the Secretary, CDC, FDA, Health Resources and Services Administration, National Institutes of Health, and others as deemed appropriate by the Secretary or designee.

As necessary, standing and ad hoc subcommittees composed of members of the parent committee may be established to perform specific functions within the Committee's jurisdiction.

The DHHS Committee Management Officer shall be notified upon establishment of each standing subcommittee and shall be provided with information on its name, membership, function, and estimated frequency of meetings.

Members shall be invited to serve for overlapping four year terms; terms of more than two years are contingent upon the renewal of the Committee by appropriate action prior to its termination. Members may serve after the expiration of their term until their successors have taken office.

The Committee shall be able to call upon special consultants, assemble ad hoc working groups and convene conferences and workshops as necessary to assist in the work of the Committee.

Management and support services shall be provided by the Office of Science Policy, Office of the Director, National Institutes of Health, with direction and guidance from the Assistant Secretary for Health.

Meetings

Meetings shall be held approximately three times per year at the call of the Chair with the advance approval of a Government official who shall also approve the agenda. A Government official shall be present at all meetings.

A quorum for the conduct of business by the Committee shall be ten of the appointed members.

Meetings shall be open to the public except as determined otherwise by the Secretary or designee; notice of all meetings shall be provided to the public.

Meetings shall be conducted, and records of the proceedings kept, as required by applicable Federal laws and regulations and Departmental policies.

Compensation

Members shall be paid at a rate not to exceed the daily equivalent of the rate in effect for Executive Level IV of the Executive Schedule for each day they are engaged in the performance of their duties as members of the Committee. Members shall receive per diem and travel expenses as authorized by section 5703, Title 5 U.S.C., as amended, for persons employed intermittently in the Government service. Members who are officers or employees of the United States shall not receive compensation for service on the Committee.

Annual Cost Estimate

The estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support, is \$200,070. The estimated annual person-years of staff support required is 2.5, at an estimated annual cost of \$149,838.

Reports

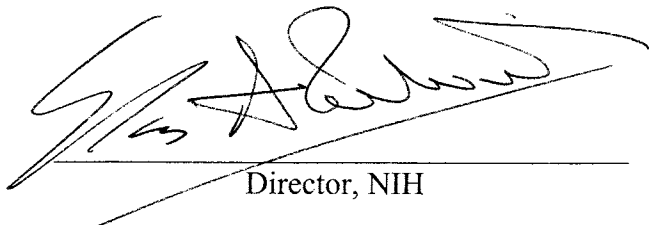
In the event a portion of a meeting is closed to the public, an annual report shall be prepared which shall contain, at a minimum, a list of the members and their business addresses, the Committee's function, dates and places of meetings, and a summary of the Committee's activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

Termination Date

Unless renewed by appropriate action prior to its expiration, the Secretary's Advisory Committee on Xenotransplantation shall terminate on July 10, 2005.

Approved:

6/30/03
Date



Director, NIH